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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT			ATTY. DOCKET NO. 20784/6	NO. SERIAL NO. 10/082,001			
				APPLICANT(S): Demuth et al.			
				FILING DATE: February 22, 2002		ART UNIT: -1646-1653	
			UNITED STATE	S PATENT DOCUMENTS			
EXAM. INITIAL		DOCUMENT NUMBER	DATE	INVENTOR	CLASS	SUB CLASS	FIL. DATE IF APPR
CMK	AA	2,961,377	11/22/1960	Shapiro et al.	167	65	
	AB	3,174,901	03/23/1965	Sterne	167	65	
	AC	3,879,541	04/22/1975	Kabbe et al.	424	326	
	AD	3,960,949	06/01/1976	Ahrens et al.	260	564 B	
	AE	4,028,402	06/07/1977	Fischer et al.	260	501.14	
	AF	4,935,493	06/19/1990	Bachovchin et al.	530	331	
	AG	5,433,955	07/18/1995	Bredehorst et al.	424	94.3	
	AH	5,462,928	10/31/1995	Bachovchin et al.	514	19	
	AI	5,512,549	4/30/1996	Chen et al.	514	12	
	AJ	5,543,396	08/06/1996	Powers et al.	514	19	}
	AK	5,614,379	03/25/1997	MacKellar	435	68.1	
	AL	5,624,894	04/29/1997	Bodor	514	2	
	AM	5,939,560	08/17/1999	Jenkins et al.	548	535	
CMK	AN	6,006,753	12/28/1999	Efendic	128	898	
			FOREIGN P	ATENT DOCUMENTS			
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRAN Y/N
CMK	BA	WO 01/62266 A2	08/30/2001	PCT	A61K	38/00	Y
	ВВ	WO 00/53171	09/14/2000	PCT	A61K	31/155	Y
	BC	DT 25 42 598 A1	04/22/1976	Germany	C07C	129/16	N
	BD	FR 2 696 740 A1	04/15/1994	France	C07D	207/404	N
	BE	FR 2 085 665	12/31/1971	France	A61K	27/00	N
CMK	BF	WO 97/40832	11/06/1997	PCT	A61K	31/425	Abstract only
Examiner:		Chlip	-	Date:	8/03		



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INFORMATION DISCLOSURE STATEMENT

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APPLICANT(S): Demuth et al.

FILING DATE: February 22, 2002 ART UNIT: 1646

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRAN Y/N
CME	BG	WO 95/15309	06/08/1995	PCT	C07D	<del>207/1</del> 6	Y
	ВН	JP 4334357	11/20/1992	Japan	C07C	<del>-233/57 -</del>	Abstract only
	ві	WO 93/08259	04/29/1993	PCT	C12N		Y
	вј	WO 95/11689	05/04/1995	PCT	A61K	37/00-	Y
	вк	WO 97/45117	12/04/1997	PCT	A61K	31/435	Y
	BL	DE 196 16 486 C2	10/30/1997	Germany	. A61K	<del>45/0</del> 0	Y
	ВМ	WO 95/29691	11/09/1995	PCT	A61K	38/00	, <b>Y</b>
	BN	WO 98/22494	05/28/1998	PCT	- <del>C07K</del> -	5/06	Y
	во	· WO 00/01849	01/13/2000	PCT	G <del>12Q</del>	1/68	Y
	BP	EP 0 658 568 A1	06/21/1995	EPO	C07K	14/605-	Y
CMK	BQ	DD 296 075 A5	11/21/1991	Germany	C07D	295/04	Y
	BR	DD 296 075 A5	11/21/1991	Germany	C07D	295/04	N
CMK	BS	EP 0 708 179 A2	04/24/1996	ЕРО	C12N	<del>15/16</del>	Y
÷	ВТ	EP 0 995 440 A1	04/26/2000	EPO	A61K	31/425	N-
CMK	BU	WO 91/11457	08/08/1991	PCT	Ç07K	7/34	Y
1	BV	WO 91/16339	10/31/1991	PCT	C07K	5/10	Y
	BW	WO 98/19998	05/14/1998	PCT	C07D	207/00	Y
	вх	WO 91/17767	11/28/1991	PCT	AGIK	37/54	Y
	BY	JP 04-288098	10/13/1992	JР	A61K-	37/64	(Abstract Only)
CMK	BZ	WO 99/46272 A	09/16/1999	PCT	C07F	9/572	Y
÷	BAA	DE 299 09 210 U	09/09/1999	Germany	A61K	31/425	<del>N</del> —
Examiner:		Chile		Date: 12/0	6/02		

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OCHTER 1600/2900 PRADEN **FORM PTO-1449** ATTY. DOCKET NO. SERIAL NO. INFORMATION DISCLOSURE STATEMENT 10/082,001 20784/6 APPLICANT(S): Demuth et al. FILING DATE: ART UNIT: February 22, 2002 1646 OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.) CA Campbell, I.W. New Antidiabetic Drugs, ed. C.J. Bailey & P.R. Flatt, Smith-Gordon, "Sulphonylureas and metformin: CMK efficacy and inadequacy". 3:33-51 (1990). The Merck Index, 11th Edition, An Encyclopedia of Chemicals, Drugs, and Biologicals, 1989, Page 934 CB The Merck Index, 12th Edition, An Encyclopedia of Chemicals, Drugs, and Biologicals, 1996, Page 1014. CC Martindale The Extra Pharmacopoeia, 30th Edition, London Pharmaceutical Press, 1993, Page 1619. CD Martindale The Extra Pharmacopoeia, 30th Edition, London Pharmaceutical Press, 1993, Page 36. CE CHEMICAL ABSTRACTS, vol. 115. No. 15, 14. October 1991 (1991-10-14) Columbus, Ohio, US; abstract no. CF 149947q, SCHOEN EKKEHARD ET AL: "Dipeptidyl peptidase IV in the immune system. Effects of specific enzyme inhibitors on activity of dipeptidyl peptidase IV and proliferation of human lymphocytes" CG CHEMICAL ABSTRACTS, vol. 126, no. 2, 13. January 1997 (1997-01-13) Columbus, Ohio, US; abstract no. 16161j. STOECKEL A. ET AL: "Competitive inhibition of proline specific enzymes by amino acid thioxopyrrolidides and thiazolidides". CHEMICAL ABSTRACTS, vol. 118, no. 25, 21. June 1993 (1993-06-21) Columbus, Ohio, US; abstract no. 255342k, CH Hosoda, et al, "Preparation of N-(heterocyclic Carbonyl) Amino Acids and Analogs as Prolyl Endopeptidase Inhibitors", November 1992 (1992-11-20) ARAI ET AL., "Synthesis of prolyl endopeptidase inhibitors and evaluation of their structure-activity relationships: in CI vitro inhibition of prolyl endopeptidase from Canine Brain" CHEMICAL AND PHARMACEUTICAL BULLETIN., Bd. 41, No. 9, 1993, pages. 1583-1588. J. Lin et al.: "Inhibition of depeptidyl peptidase IV by fluoroolefin-containing n-peptidyl-O-hydroxylamine CJ peptidomimetics" PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF USA, Vol. 95, November 1998, pages 14020-14024. KOROM, S., et al "Inhibition of CD26/dipeptidyl peptidase IV activity in vivo prolongs cardiac allograft survival in rat CK recipients", Transplantation, Vol. 63, 1495 - 1500 No. 10 (1997) CL TANKA, S., et al., "Suppression of arthritis by the inhibitors of dipeptidyl peptidase IV". Int. J. Immunopharmacol, Vol. 19, No. 1 Pages 15-24, (1997) CM MENTLEIN, R., et al., "Proteolytic processing of neuropeptide Y and peptide YY by dipeptidyl peptidase IV". Regul. Pept. 49, 133 -144 (1993) CN WETZEL, W., et al., "Effects of the CLIP fragment ACTH 20-24 on the duration of REM sleep episodes". Neuropeptides, 31, 41-45 (1997) CO AMASHEH, S., et al., "Electrophysiological analysis of the function of the mammalian renal peptide transporter expressed in Xenopus Laevis oocytes". J. Physiol. 504, 169-174 (1997) CP DURINX, C.; et al.; "Reference Values for Plasma Dipepidyl-Pepidase IV activity and their Association with Other Laboratory Parameters". Clin Chem Lab Med 2001, February; 39 (2):155-9, 1 page. Examiner: Date:



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## TECH CENTER 1600/2900

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT			ATTY. DOCKET NO. 20784/6	SERIAL NO. 10/082,001		
		·	APPLICANT(S): Demuth et al.			
			FILING DATE: February 22, 2002	ART UNIT: 1646		
		OTHER DOCUMENTS (INCLUDING AU	THOR, TITLE, DATE, PERTINEN	T PAGES, ETC.)		
· CMK	CQ	GOSSRAU, R.; "Cytochemistry of Membrane	Proteases". Histochem J, 1985, July;	17 (7):737-71, 1 page.		
,	CR	HAHN, T.; et al.; "Enzyme Histochemical Evidence for the Presence of Potential Blood Pressure Regulating Proteases in Cultured Villous Explants from Human First Trimester Placentae". Acta Histochem 1993, December, 95 (2):185-92, 1 page.				
	CS	HEYMANN, E. et al., "Has Dipeptidyl Peptidase IV an Effect on Blood Pressure and Coagulation." Klin Wochenschr, 1984, January, 2;62 (1):2-10, 1 page.				
	СТ	MAGYAR, C.E. et al., "Proximal Tubule Na T Hypertension." <u>Am J. Physiol Renal Physiol</u> ,	Transporter Responses are the same du 2000, August; 279 (2) :F358-69, 1 pag	ring Acute and Chronic e.		
	CU	PAPIES, B. et al., "Isoenzyme (Lactate Dehyd Activity Changes in Blood Plasma Likely India 1991; 33 (3):218-26, 1 page.	rogenase, Aspartate Aminotransferase, cative of Organ Involvement due to Ar	) and Dipeptidyl Peptidase IV terial Hypertension." <u>Cor Vasa</u> ,		
	CV	QURESHI. N.U.; et al., "Endogenous Neuropeptide Y Mediates Vasoconstriction during Endotoxic and Hemorrhagic Shock". Regul Pept, 1998, September 25; 75-76:215-20, 1 page.				
	CW	Index Nominum, International Drug Directory 1992/1993, Medpharm Scientific Publishers, pages 728-729.				
	CX	The Merck Index, An Encyclopedia of Chemicals and Drugs, 9th Edition, Merck & Co., Inc., 1976, page 773				
	CY	Willms et al., <u>Journal of Clinical Endocrinology Metabolism</u> , "Gastric Emptying, Glucose Responses, and Insulin Secretion after a Liquid Test Meal: Effects of Exogenous Glucagon-Like Peptide-1 (GLP-1)-(7-36) Amide in Type 2 (Noninsulin-Dependent) Diabetic Patients", 1996, 81(1): 327-332.				
	CZ	Hoffmann et al., <u>Journal of Chromatography A</u> , "Inhibition of dipeptidyl peptidase IV (DP IV) by anti-DP IV antibodies and non-substrate X-X-Pro- oligopeptides ascertained by capillary eletrophoresis", 1995, 716:355-362.				
	CAA	C.B. Welch, Medical Management of Non-Insulin-Dependent (Type II) Diabetes, 3 <sup>rd</sup> edition, American Diabetes Association, "Diagnosis and Classification" p. 3, 1994, Pharmacologic Intervention (2 pages).				
	CAB	Mannucci et al., <u>Diabetes Care</u> , "Effect of Metformin on Glucagon-Like Peptide 1 (GLP-1) and Leptin Levels in Obese Nondiabetic Subjects", 24(3): 489-494, March 2001.				
	CAC	Stryer, Biochemistry 3 <sup>rd</sup> Ed., "Protein Conformation, Dynamics, and Function", 1988, p 191-193.				
	CAD	Pauly et al., Regulatory Peptides, "Abstracts Issue: Abstracts from the 11 <sup>th</sup> International Symposium on Regulatory Peptides", July 15, 1996, 64(1-3): 148 plus cover.				
	CAE	Gutniak et al., New England Journal of Medicine, "Antidiabetogenic Effect of Glucagon-like peptide-1 (7-36) Amide in Normal Subjects and Patients With Diabetes Mellitus", 1992, 326: 1316-1322.				
CMK	CAF	Hendrick et al., Metabolism - Clinical and Experimental, "Glucagon-like Peptide-I-(7-37) Suppresses Hyperglycemia in Rats", January 1993, 42(1): 1-6.				
Examine	xaminer: Date: 1/8/03					



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1.8	HADEMAR NFORM	FORM PTO-1449 ATION DISCLOSURE STATEMENT	ATTY: DOC	KET NO.	SERIAL NO. 10/082,001		
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		34	FILING D February 2		ART UNIT: 1646		
		OTHER DOCUMENTS (INCLUDING A	UTHOR, TITLE, DA	TE, PERTINEN	T PAGES, ETC.)		
·CMK	CAG	Nauck et al., <u>Diabetologia</u> , "Normalization o in Type 2 (non-insulin-dependent) diabetic p	f fasting hyperglycaem atients", (1993), 36: 74	nia by exogenous į 11-744.	glucagon-like peptide 1 (7-36 amide)		
./	САН	Gutniak et al., <u>Diabetes Care</u> , "Subcutaneous Postprandial Glycemia in NIDDM", Septem			agon-Like Peptide 1 Abolishes		
	CAI	Deacon et al., <u>Journal of Clinical Endocrinol</u> Plasma in Vitro Yields and N-Terminally Tre 80(3): 952-957.					
	CAJ	H.A. Smith et al., Veterinary Pathology (four (1972), p 1018-1020.	rth edition), "Diseases	and Disorders of I	Metabolism: Deficiency Diseases",		
	CAK	G.G. Duncan, Diseases of Metabolism (Asia	n edition), "Diabetes M	fellitus", (1966), p	951-957.		
	CAL	T.J. Kieffer et al., "Degradation of Glucose-In Vitro and In Vivo by DP IV", Endocrinole			Truncated Glucagon-Like Peptide 1		
	CAM	<ul> <li>C.F. Deacon et al., <u>Diabetes</u>, "Both Subcutaneously and Intravenously Administered Glucagon-Like Peptide I Are Rapidly Degraded from the NH<sub>2</sub>-Terminus in Type II Diabetic Patients and in Healthy Subjects", September 1995, 4 1126-1131.</li> <li>Pauly et al., <u>Metabolism</u>, "Improved Glucose Tolerance in Rats Treated with the Dipeptidyl Peptidase IV (CD26) Inhibitor Ile-Thiazolidide", (1999), 48(3): 385-389.</li> </ul>					
	CAN						
	CAO	Vidal, (1993), 69th Edition, p. 612-613.					
	CAP	CAP Goodman & Gilman's The Pharmacological Basis of Therapeutics, Ninth Edition, (1996), p. 1510.					
CAQ Nathan et al., <u>Diabetes Care</u> , "Insulinotropic Action of Glucagonlike Peptide-1-(7-37) in Diabeti Subjects", February 1992, 15(2): 270-275.				) in Diabetic and Nondiabetic			
	CAR	Pschyrembel, Kininisches Wörterbuch 257,	Auflage, (1994), 9 page	s.			
	CAS		al., <u>Journal of Clin. Invest.</u> , "Rapid Enzymatic Degradation of Growth Hormone-releasing Hormone by itro and in Vivo to a Biologically Inactive Product Cleaved at the NH <sub>2</sub> Terminus", Volume 78, October 1986,				
	CAT	Snow et al., Advances In Medicinal Chemist Immunosuppressive Agents", Vol. 3, (1995),		bitors of Dipeptid	yl Peptidase IV: A New Class of		
	CAU	Thorens et al., <u>Diabetes</u> , "Glucagon-Like Pepetide-I and the Control of Insulin Secretion in the Normal State and in NIDDM", (1993), 42:1219-1225.					
	CAV	Wakselman et al., "Inhibition of HIV-1 infection of CD 26 <sup>+</sup> but not CD 26 <sup>-</sup> cells by a potent cyclopeptidic inhibitor of th DPP IV activity of CD26", Abstract P 44 of the 24 <sup>th</sup> European Peptide Symposium, (1996).					
CMK	CAW	Ashworth et al., <u>BIOORG. MED. CHEM. LI</u> Peptidase IV", (1996), 6(10): 1163-1166.	ETT., "2-Cyanopyrrolic	lides as Potent, St	able Inhibitors of Dipeptidyl		
Examir	ier:	Chil	Dat	e: 1 <sup>2</sup> /6	103		

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT			ATTY, DOCKET NO. 20784/6	SERIAL NO. 10/082,001		
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		OTHER DOCUMENTS (INCLUDING AU	THOR, TITLE, DATE, PERTINEN	IT PAGES, ETC.)		
. CMK	CAX Endroczi et al., <u>ACTA PHYSIOL. HUNG.</u> , "Dipeptidyl peptidase IV (DP IV) and Superoxide Dismutase Activity in Thymus-Derived Lymphocytes: Effects of Inhibitory Pepdides and Zn <sup>2+</sup> in Vitro", (1990), 75(1): 35-44.					
	CAY	Lee, H.S. et al., "Cathepsin B Inhibitory Peptides Derived from β-Casein," Peptides 21 (2000) 807-809.				
	CAZ	Edwards, J.V. et al., <u>J. Peptide Res.</u> , "Synthesis and Activity of NH <sub>2</sub> - and COOH-Terminal Elastase Recognition Sequences on Cotton," (1999), 54: 536-543.				
	CBA Wettstein, J.G. et al. <u>Pharmacology &amp; Therapeutics</u> , "Central Nervous System Pharmacology of Neuropeptide Y.", (1995), 65(3): 397-414.					
	CBB	Badia-Elder N.E. et al., <u>Alcoholism Clinical and Experimental Research</u> , "Effects of Neuropeptide Y (NPY) on Ethanol Intake and Anxiety in High and Low Alcohol Drinking (HAD1/LAD1) Rats", (2000), 24(5): 82A.				
CMK	СВС	Munglani R. et al., Drugs, Adis International Ltd, At, "The Therapeutic Potential of Neuropeptide Y Analgesic, Anxiolytic and Antihypertensive", (1996) 52(3): 371-389.				
Examine	er:	Chip	Date: 2/0/0	· · · · · · · · · · · · · · · · · · ·		

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